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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,161	04/26/2001	Hidetaka Iwai	206580US0	6889
22850	7590	10/02/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/02/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/842,161

Applicant(s)

IWAI ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of Amendment filed on July 11, 2003. Claim objections are maintained for the reasons of record. Claim rejections under 35 U.S.C. § 103 (a) have been modified to meet the amended limitation and new claims. Claims 1, 2, 4-28 are pending.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites "alkyl glutamic acid". The only glutamic acid derivatives disclosed in the specification is N-acyl glutamic acid salts including "monosodium N-lauroyl glutamate, disodium N-stearoyl glutamate, monosodium N-stearoyl-L-glutamate". See p.4-5, bridging par.; Table 4. While the declaration filed on December 24, 2002, indicates that "sodium alkyl glutamate" is used to compare the claimed invention from the prior arts. It is not clear, from the applicants' disclosure in specification, declaration, and the instant claims, what the scope of the limitation "alkyl glutamic acid" is. It is not clear whether the term encompasses N-acyl glutamic acid salts as disclosed in the specification and the prior art, or the does not encompass the acyl glutamic acid salts, which are not supported by applicants' original disclosure.

#### ***Claim Objections***

Claims 6, 7, and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claims 6, 7, and 8 fail to further limit the subject matter since the claims recite mere intended use and purpose of use of the composition of claim 1. See MPEP 2111.02.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3, 6-8, 10-21, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (English Translation of JP 63-126542 provided herewith).

Yu teaches transparent microemulsions containing hydrophilic ionic surfactants and oil components used for pharmaceuticals and cosmetics. See p. 2, lines 1 –17; p. 7, lines, 9-10. The reference teaches that the ratio of the nonionic surfactant to the oil ingredients in the invention may range from 1:05 to 1:10, and the emulsified particle size is 0.01-0.1 microns. See instant claims 1 and 3. See p. 4, lines 11-12. The application of the invention, such as liquid detergent, shampoo, hair tonic, etc, are disclosed in p. 7, lines 19-24. See instant claims 19.

Although Yu lacks a specific example formulation having the ratio of oil to hydrophilic surfactants, which is greater than or equal to 10:1, the ratio of 10:1 is

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taught to be useful. Thus, one having ordinary skill in the art at the time of the invention was made would have had expected to successfully formulate a transparent microemulsion having such high oil to hydrophilic surfactant ratio.

The reference teaches anionic surfactants, cationic, amphiphilic surfactants, or mixture of thereof in p. 4, line 12 – p. 5, line 5. See instant claims 11-13. The reference teaches N-acylglutamic acid salts and recites monosodium N-lauroyl glutamate, disodium N-stearoyl glutamate, monosodium N-myristearyl-L-glutamate. See p. 4, fifth paragraph; instant claims 27. The reference also teaches N-myristoyl-N-methyltaurine. See instant claim 26. While the Yu reference does not teach dynamic surface tension of these surfactants, examiner notes that the prior art surfactants are same compounds used in applicants' invention, and thus believes that the dynamic surface tension is the same.

Examiner also notes that instant claims 1, 6, 7, and 15 are product-by-process claims. It is well settled in patent law that "if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP § 2113, quoting In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, given the presumption of the obviousness of the product itself, the process of making thereof will not be given patentable weight. Nevertheless, the limitations are obvious view of the Yu reference teaching, in p. 7, lines 4- 8, to use a high pressure homogenizer or ultrasound emulsifying machine to produce strong shear stress of 400 atm or higher, or preferably of 600 atm or higher at a temperature below 50 °C. See

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instant claim 20. Examiner takes the position that employing the prior art equipments would obviously produce the shearing rate of the instant claims, unless proven otherwise.

2. Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1, 2, 6-8, 10-21, 26, and 27 above, and further in view of Drapier et al. US 6121228 ("Drapier").

Yu further teaches that while liquid oils are preferred, oils in solid state may be used if they become liquid when mixed, suggesting mixing liquid and solid fatty components. See p. 5, line 6 – p. 6, last line. See also Tables for high alcohols, such as isostearyl alcohol, showing satisfactory transparent microemulsions. The Yu reference fails to teach an example of composition having both solid and liquid oil with specific viscosity.

Drapier teaches water-in-oil microemulsion liquid detergent having viscosity ranging from 6-300 milliPascal. See col. 4, lines 47 – 67; col.14, lines 17 - 26.

Given the teaching in Yu that the both liquid and solid oils may be used for variety of microemulsion applications such as liquid detergents, and the teaching that thickening agents may be added in the compositions, it would have been obvious to one having ordinary skill in the art to have expected successfully producing a product having desired viscosity by routine experimentations. The routineer who contemplates to formulate the liquid detergent according to Yu would have been motivated to adjust the viscosity as taught by Drapier.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery Systems, 1990 5<sup>th</sup> ed.).

While Yu teaches that the HLB of the ionic surfactants should be hydrophilic since it is necessary to obtain oil-in-water type microemulsions, the reference fails to teach HLB of the surfactants.

Ansel teaches that surfactants having HLB of 8-18, and particularly HLB of 15-18 produce transparent microemulsion compositions. See Ansel, p. 244 col. 2, lines 9-13.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Ansel for specific types and characteristics of the emulsifiers conventionally used in microemulsions.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Gers-Barlag et al. (US 5876702) ("Gers-Barlag").

The Yu reference fails to teach the surface tension of the oil components.

Gers-Barlag teaches that o/w microemulsions are obtained from oil components having surface tension of less than 30 mN/m. See col. 17, lines 15

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– 30. The reference teaches that oils having a polarity between 10-20 mN/m are preferred. See also col. 17, lines 31 – 46 for specific types of oils.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Gers-Barlag for specific types and characteristics of oils conventionally used in microemulsions.

5. Claims 23 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yu as applied to claims 1-4, 6-8, 10-21, 26, and 27 above, and further in view of Diec et al. (US 6468551 B1) ("Diec").

Yu, discussed above, fails to teach using silicone oil in the microemulsion. Diec teaches cosmetic o/w microemulsions comprising hydrophilic o/w emulsifiers. See Example 22, comprising oil and the emulsifier in the weight ratio of greater than 10:1. See also col. 45, lines 31-39. The reference teaches that silicone oils are "advantageously" used in the invention, particularly mentioning polydimethylsiloxanes. See col. 25, lines 43 – 53. See instant claim 23 and 25.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Diec for specific types oils conventionally used in microemulsions for cosmetic purposes. The skilled artisan would have expected to successfully produce a cosmetically advantageous composition.



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6. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, 10-21, 26, and 27 above, and further in view of Brunetta et al. (US 5562911) ("Brunetta").

Yu, discussed above, fails to teach fluoro-based oil.

Brunetta teaches that due to the formation of protective film on skin, the use of perfluoropolyether in cosmetic formulation is well known in the art. See col. 1, lines 15 – 56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substitute the oil in the Yu formulation with perfluoropolyether as motivated by Brunetta, because of the expectation of successfully producing a o/w microemulsion which forms protective film on the skin.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, 10-21, 26, and 27 above, and further in view of Shiojima et al. (US 6066316) ("Shiojima").

While the Yu reference teaches that nonionic surfactants are used to make microemulsions, the reference fails to teach polyoxyethylene alkyl ethers. See translation, p. 2, 3<sup>rd</sup> par.

Shiojima teaches a transparent oil-in-water hair cosmetic composition comprising POE behenyl ether. See col. 48, Test Example 22. The formula contains 32.5 % by weight of oil phase (Carnauba wax and liquid petrolatum) and 3.0 % of POE-10 behenyl ether, meeting the weight ratio requirement of instant claim 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Yu by substituting the hydrophilic surfactants with POE-10 behenyl ether as motivated Shiojima because of an expectation of successfully producing cosmetic compositions with similar effects or hair cosmetic emulsion compositions.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4-28 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' declaration filed on December 24, 2002, has been considered but is not persuasive for the reasons stated above. To rebut the presumption of obviousness, applicants must show unexpected results of the invention by clear and convincing evidence that commensurate with the scope of the claims. See MPEP § 716.02. Applicants indicate that the prior art surfactants used in the example formulation have surface tension slightly above 57 mN/m, and suggest that low transparency is obtained by using these surfactants in a particular formulation shown in declaration p. 2. In this case, examiner takes the position that the declaration is not commensurate with the scope of the claims and not persuasive because it does not specify what surface active agents have the dynamic surface active agents below 57m/Nm. For example, the declaration on p. 2 show the dynamic surface tensions for "alkyl glutamate sodium", "POE alkyl ether", and "alkyl methyl taurin sodium". The declaration suggests that the entire class of surfactants have the same dynamic surface active agents, which cannot be true. See, for example, the different dynamic surface tensions for alkyl

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trimethylammonium halide (myristyl trimethylammonium chloride and cetyltrimethylammonium bromide) as disclosed by applicants' declaration on p. 4. Furthermore, the declaration does not show that applicants had cationic surfactants having the required dynamic surface tension. See instant claim 12.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

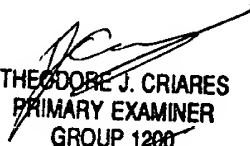
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner

  
THEODORE J. CRIARES  
PRIMARY EXAMINER  
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1600